

DRUG POLICY

Non-Formulary Exception

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

Non-Formulary exception criteria set forth in this Policy applies to formularies which do not include the requested product(s) on the formulary drug list. The intent of the non-formulary exception criteria is to outline the conditions under which a non-formulary medication may be eligible for coverage through the prescription drug benefit. It should be applied alongside any relevant policies pertaining to the specific medication, depending on the member's benefit plan. For certain product categories, additional requirements are detailed within the approval criteria.

POLICY

Required Documentation (where applicable)

Submission of the following information is necessary to initiate the formulary exception request:

1. Documentation of prior Wellmark formulary exception approval letter for the requested medication.
2. Chart notes or medical records documenting that the patient is unable to take all formulary alternatives for the given diagnosis due to inadequate treatment response, intolerance, or contraindication including name of medication(s) tried, dates of trial(s) and reason for treatment failure(s), intolerance and/or contraindication whichever are applicable.
3. Chart notes or medical records documenting the clinical condition for which there is no formulary alternative or the listed formulary alternatives are not recommended based on published guidelines or clinical literature OR the formulary alternatives will likely be ineffective or less effective for the patient OR the formulary alternatives will likely cause an adverse effect.
4. Chart notes or medical records documenting that the patient is unable to swallow the formulary alternatives(s) and requires use of a specific dosage form due to one of the following: age, dysphagia, oral/motor difficulties, or medications are administered through a feeding tube.

5. Documentation that the prescribed quantity falls within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature including name of medication, quantity, strength, directions, and duration requested.

Non-Formulary Exception Criteria for Initial Approval

1. The requested drug may be considered medically necessary when the following criteria is met:
 - A. The requested drug an anticonvulsant or antipsychotic medication that the member is established on and stopping or changing the medication would cause unacceptable outcomes to the member's health.
OR
 - B. The member meets ALL of the following criteria:
 - i. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
 - ii. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
 - iii. One of the following:
 1. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.
OR
 2. The member is unable to swallow the formulary alternative(s) and requires use of a specific dosage form (examples: suspension, solution, injection) due to one of the following: A) Age, B) Dysphagia, C) Oral/Motor difficulties, D) Medications are administered through a feeding tube. Documentation is required and must include chart note(s) or other documentation indicating the member is unable to swallow the formulary alternative(s) and requires use of a specific dosage form.

Approval will be for the FDA-Approved duration of treatment OR a duration of treatment supported in the compendia of current literature **not to exceed 12 months.**

Continuation of Therapy

1. The request for continuation of therapy may be considered medically necessary when ALL initial authorization criteria are met AND clinical documentation is provided showing the patient has achieved and/or maintained a positive clinical response with the requested therapy.

Approval will be for the FDA-Approved duration of treatment OR a duration of treatment supported in the compendia of current literature **not to exceed 12 months.**

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

POLICY HISTORY

Policy #: 05.06.11

Original Effective Date: January 12, 2016

Reviewed: October 2025

Revised: October 2025

Current Effective Date: December 11, 2025